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(54) Title: APPARATUS AND METHOD FOR ELONGATION OF A PAPILLARY MUSCLE

(57) Abstract: A system and method for treating a dilated heart valve by elongating a papillary muscle. The system comprises a delivery catheter (110) and a holding catheter (130). The system further comprises a muscle elongation device (200) including at least two clamping rings (210), (215) slidably connected by at least one connecting rod (220). The muscle elongation device (200) is delivered to a papillary muscle (560) associated with the dilated heart valve, where it is released from the delivery catheter (110) and the clamping rings (210), (215) wrap about and engage the papillary muscle. The muscle tissue is cut between the clamping rings (210), (215), which then move away from each other to a predetermined position, thus permitting the papillary muscle to elongate.

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APPARATUS AND METHOD FOR ELONGATION OF A PAPILLARY MUSCLE

TECHNICAL FIELD

[0001] The technical field of this disclosure is medical devices, particularly, for treating mitral valve regurgitation.

BACKGROUND OF THE INVENTION

[0002] Heart valves, such as the mitral valve, are sometimes damaged by disease or by aging, which can cause problems with the proper function of the valve. Heart valve problems generally take one of two forms: stenosis, in which a valve does not open completely or the opening is too small, resulting in restricted blood flow; or insufficiency, in which blood leaks backward across the valve that should be closed. Valve replacement may be required in severe cases to restore cardiac function.

[0003] In various types of cardiac disease, mitral valve insufficiency may result. Any one or more of the mitral valve structures, i.e., the anterior and posterior leaflets, the chordae tendineae, the papillary muscles or the annulus may be compromised by damage from disease or injury, causing the mitral valve insufficiency. Typically, in cases where there is mitral valve insufficiency, there is some degree of annular dilatation resulting in mitral valve regurgitation. Mitral valve regurgitation occurs as the result of the leaflets being moved back from each other by the dilated annulus. Without correction, mitral valve regurgitation may lead to disease progression and/or further annular dilatation and worsening of the insufficiency.

[0004] Although mitral valve repair and replacement surgery can successfully treat many patients with mitral valve insufficiency, techniques currently in use are attended by significant morbity and mortality. Most valve repair and replacement procedures require a thoractomy to gain access into the patient's thoracic cavity. Surgical intervention within the heart generally

requires isolation of the heart and coronary blood vessels from the remainder of the arterial system and arrest of cardiac function. Open chest techniques with large sternum openings are typically used. Patients undergoing such techniques often have scarring retraction, tears or fusion of valve leaflets as well as disorders of the subvalvular apparatus. It would be desirable, therefore, to provide a method and device for reducing mitral valve regurgitation that would overcome these and other disadvantages.

SUMMARY OF THE INVENTION

[0005] The invention provides an apparatus and method for elongation of a papillary muscle to provide more complete closure of a dilated heart valve. An implantable muscle elongation device can be delivered by a catheter, thus avoiding the significant morbity and mortality associated with open chest surgical techniques used in cardiac valve repair.

[0006] A first aspect of the invention provides a system for treating a dilated heart valve comprising a delivery catheter, a holding catheter and a muscle elongation device. The muscle elongation device is held by the holding catheter and received in the delivery catheter, the muscle elongation device including at least two clamping devices slidably connected by at least one connecting rod. When the system is delivered to a papillary muscle associated with the dilated heart valve, the muscle elongation device is released from the holding catheter and the clamping devices wrap about the papillary muscle, the papillary muscle is cut and the clamping devices move away from each other along the at least one connecting rod in response to the tension between the papillary muscle base and the valve annulus.

[0007] A second aspect of the invention provides a method for treating a dilated heart valve. The method comprises delivering a muscle elongation device through a lumen of a catheter to a location adjacent a papillary muscle associated with a dilated heart valve. The muscle elongation device having at least two clamping devices disposed along at least one connecting rod is released from the catheter to wrap the clamping devices about the papillary muscle. The method additionally comprises cutting the muscle between the

clamping devices and sliding the clamping devices away from each other along the connecting rod.

[0008] Yet another aspect of the invention provides a muscle elongation device for treatment of a dilated heart valve. The device comprises at least two clamping devices disposed along at least one connecting rod. The clamping devices clamp a muscle tissue and slide along the connecting rod to create a muscle elongation site.

[0009] The foregoing and other features and advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying drawings. The drawings are not drawn to scale. The detailed description and drawings are merely illustrative of the invention, rather than limiting the scope of the invention being defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[00010] **FIG. 1** shows a delivery system for treating a dilated heart valve in accordance with the present invention;

[00011] **FIG. 2** shows a muscle elongation device for a system for treating a dilated heart valve in accordance with the present invention;

[00012] **FIG. 3** shows another embodiment of a delivery catheter for a system for treating a dilated heart valve in accordance with the present invention;

[00013] **FIGS. 4** to **7** illustrate the placement of the device of **FIGS. 1** to **2**; and

[00014] **FIG. 8** is a flowchart illustrating a method of elongation of a papillary muscle in accordance with another aspect of the invention.

DETAILED DESCRIPTION OF THE PRESENTLY PREFERRED EMBODIMENT

[00015] **FIGS. 1-2** illustrate a system for treating a dilated heart valve by deploying a muscle elongation device to a papillary muscle. The muscle elongation device can be delivered percutaneously through a delivery catheter using a holding catheter or other mechanical means to deploy and expand the muscle elongation device. Alternatively, the muscle elongation device can be delivered surgically using any known surgical technique including, but not limited to, thoracotomy, sternotomy and open cardiac surgical techniques.

[00016] **FIG. 1** illustrates delivery catheter **110** used to deploy the system disclosed herein at **100**. The invention may be practiced, however, with any appropriate means for delivering the device to a desired location for papillary muscle elongation. In one example, the device is implanted in the left ventricle via the aorta (see **FIG. 6**). In one embodiment, a guide catheter **150** provides a pathway for advancing delivery catheter **110** to the target muscle. The use of guide catheters are well known to those with skill in the art.

[00017] Those skilled in the art will appreciate that numerous paths are available to gain access to a papillary muscle site. For surgical approaches with an open chest or open heart, a trocar or cannula may be inserted directly in the superior vena cava or the aortic arch. The delivery element can then follow the same path as the percutaneous procedure to reach the left ventricle, either transeptally or through the cardiac valves. Transeptal approaches, whether percutaneous or surgical, may require placement of a closure device at the transeptal puncture on removal of the delivery element after the procedure. Similar percutaneous or surgical approaches can be used to access the other cardiac valves, if the muscle elongation device is to be implanted on a papillary muscle for a cardiac valve other than the mitral valve.

[00018] Delivery catheter **110** having lumen **112** is first inserted to provide a path for the muscle elongation device **120** from the exterior of the patient to

the left ventricle (see **FIG. 4**). Holding catheter **130** releasably holds muscle elongation device **120** during advancement through delivery catheter lumen **112** to position muscle elongation device **120** for deployment at the desired location. Holding catheter **130** may also serve as a conduit for electrical current and may grip or release in response to an applied current. In one embodiment, holding catheter **130** is a push rod for deploying muscle elongation device **120** from delivery catheter **110**.

[00019] In another embodiment illustrated in **FIG. 5**, holding catheter **130** comprises a gripping device **550**. The gripping device may comprise forceps used to deliver the elongation device pictured in **FIG. 2**, and may be delivered through lumen **112** of delivery catheter **110**. In one embodiment, forceps are modified biopsy forceps that releaseably and securely grip muscle elongation device **120**. In other embodiments, forceps may also serve as a conduit for electrical current and may grip or release in response to an applied current. Forceps may also include a controller (not shown) used to control the grip or release of the forceps.

[00020] Delivery catheter **110** includes side delivery port **114** at distal end **116**. Side delivery port **114** provides an opening for placing at least a portion of the target muscle within the distal end **116** of delivery catheter **110** as shown in **FIG. 4**.

[00021] A locating device may be used to assist in accurate placement of the system disclosed herein. In one embodiment, the locating device may comprise a guide wire, as is known to those of ordinary skill in the art. In other embodiments, the locating device may comprise a soft balloon for positioning the distal end **116** of delivery catheter **110** in the apex of the ventricle. In yet other embodiments, the locating device may be a radio-opaque coating on delivery catheter **110** to assist in fluoroscopic imaging of the catheter. Although these locating devices are not shown in the attached figures, these devices are known to those of skill in the art, and further discussion is not warranted.

[00022] **FIG. 2** shows muscle elongation device **200** in accordance with one embodiment of the invention. Device **200**, as shown, comprises two clamp rings **210, 215** and two connecting rods **220**. Alternatively, muscle elongation device **200** may comprise more than two clamp rings and one or more connecting rods **220**. As shown, a first clamp ring **210** is fixed between the two connecting rods **220**, and a second clamp ring **215** is slidably mounted along the two connecting rods **220**. Connecting rods **220** are provided with stop **230** to prevent the second clamp ring **215** from sliding off the ends of connecting rods **220**. In one embodiment, stop **230** comprises enlarged ends of connecting rods **220**. In another embodiment, connecting rods **220** may include stops **235**. Stops **235** may be utilized with embodiments of muscle elongation device **200** having a first clamp ring **210** that is slidably mounted on connecting rods **220**. In yet another alternative, muscle elongation device **200** may comprise one slidable clamping ring **215**, stops **235** positioned at each end of the connecting rods 220 and stop **230**, where stop **230** acts as a fixed clamping ring. In one embodiment, ratchet teeth (not shown) are disposed along connecting rods **220** to prevent second clamp ring **215** from sliding along connecting rods **220** towards first clamp ring **210** after deployment. **FIG. 2** illustrates device **200** in a pre-deployment or delivery configuration for passage through delivery catheter **110**. In this configuration, muscle elongation device **200** has a C-shaped cross section with a slight axial separation between the two clamp rings 210, 215.

[00023] Clamp rings **210, 215** are composed of a biocompatible material comprising a metallic or a polymeric base. The material may be, for example, stainless steel, nitinol, tantalum, cobalt nickel alloy, platinum, titanium, a thermoplastic or thermoset polymer, or a combination thereof. In some embodiments, clamp rings **210, 215** comprise an elastic shape-memory material, such that clamp rings **210, 215** may be formed to assume a certain shape upon release of a constraining force. In such an embodiment, discussed below and shown in **FIG. 5**, clamp rings **210, 215** are formed to assume a clamping configuration. The clamping configuration has a substantially closed circular or ring shaped cross section that is assumed after

being restrained in an open shape (the delivery configuration). In other embodiments, clamp rings **210, 215** may comprise a thermal shape-memory material that will assume the desired end shape, clamping configuration, only with the application of heat, as by resistance heating with electrical current. In either embodiment, clamp rings **210, 215** assume the clamping configuration of a ring or circular shape after delivery of the clamping device to the desired region of the papillary muscle. Clamp rings **210, 215** have a first diameter when in the delivery configuration and a second diameter in the clamping configuration. The second diameter is less than the first diameter to effectively wrap around the target muscle. In one embodiment, clamp rings **210, 215** are between 6 and 9 millimeters in diameter when in the clamping configuration. Clamp rings **210, 215**, as shown, are rectangular in cross-section. In one embodiment, the material comprising clamp rings **210, 215** has a thickness of 0.005 to 0.010 inches (0.127 to 0.254 mm). In other embodiments, the cross-section of clamp rings **210, 215** may be square, triangular or any other appropriate shape.

[00024] Connecting rods **220** comprise a biocompatible material having a metallic or polymeric base. The material may be, for example, stainless steel, nitinol, tantalum, cobalt nickel alloy, platinum, titanium, a thermoplastic or thermoset polymer, or a combination thereof. In one embodiment, connecting rods **220** are rectangular in cross section having a thickness of 0.005 to 0.010 inches (0.127 to 0.254 mm). In one embodiment, the diameter of connecting rods **220** is less than the thickness of clamping devices **210, 215**. In another embodiment, connecting rods **220** are rectangular or square in cross-section.

[00025] **FIG. 3** illustrates another embodiment of a delivery system **300** for delivering a muscle elongation device, in accordance with the present invention. Delivery system includes delivery catheter **310**, muscle elongation device **320** and holding catheter **330**. Muscle elongation device **320** includes clamp rings **322, 324**, connecting rods (not shown) and stop **326**. In this embodiment, muscle elongation device **320** is composed of an elastic shape-memory material, such that clamp rings **322, 324** may be formed to assume a

certain shape upon release of a constraining force. Clamp rings **322, 324** may be formed to assume a substantially closed circular or ring shape after being restrained in an open shape. Delivery catheter **310** includes restraining members **340** for providing a constraining force to muscle elongation device **320**. Restraining members **340** comprise elongate members extending substantially perpendicularly from the edge of side delivery port **314**. Restraining member **340** provides the constraining force for maintaining the delivery configuration until muscle elongation device **320** is deployed.

[00026] **FIGS. 4-8** illustrate a method of using a muscle elongation device, in accordance with the present invention. **FIGS. 4-7** illustrate the delivery and placement of the muscle elongation device. **FIG. 8** is a flow chart illustrating a method of using the device shown in **FIGS. 1 - 3** in accordance with another aspect of the invention at **800**. Method **800** begins at step **805**.

[00027] First, a papillary muscle is identified as being associated with a dilated heart valve (Block **810**).

[00028] Second, the muscle elongation device of **FIGS. 1-2** is delivered to a region of the targeted papillary muscle (Block **820**). Any appropriate technique for accessing the interior of a ventricle and papillary muscles may be used. A variety of appropriate techniques is known to those of ordinary skill in the art and no further discussion is warranted. The muscle elongation device disclosed herein may be delivered through delivery catheter **110**, and a practitioner may find the aorta or vena cava to be advantageous approaches, though not an element of the invention. Other approaches are briefly discussed above in the discussion of **FIG. 1**. In one embodiment, a guide catheter is placed for advancement of the delivery catheter to the target muscle.

[00029] Referring to **FIG. 4**, side delivery port **114** permits delivery catheter **110** to be positioned around the targeted muscle region, thereby placing clamp rings **210, 215** also in a position around the targeted muscle region

(Block **830**). At delivery, the clamping devices are in the open delivery configuration, so the muscle elongation device is as pictured in **FIG. 2**.

[00030] Next, muscle elongation device **200** is deployed from delivery catheter **110** (Block **840**). In one embodiment, the device is deployed by pushing the device from delivery catheter **110** using axial force applied to holding catheter **130**. Alternatively, elongation device **200** may be held in place by holding catheter **130** while delivery catheter **110** is withdrawn. In another embodiment, holding catheter **130** may be a forceps **550**, as seen in **FIG. 5**, instead of holding catheter **130** illustrated in **FIG. 1**. In another embodiment, device **200** is deployed by retracting delivery catheter **110** from surrounding muscle elongation device **200**.

[00031] Referring to **FIG. 5**, once deployed, muscle elongation device **200** clamps around the papillary muscle **560** (Block **850**). In one embodiment of the invention, the muscle elongation device **200** comprises a shape memory material such as nitinol and upon deployment from delivery catheter **110** (Block **840**), the clamp rings **210, 215** wrap and clamp around the muscle in the clamping configuration, as shown in **FIG. 6**. Use of elastic shape-memory materials allows the clamp rings **210, 215** to wrap around the muscle by assuming the shape that has been preformed into the material. In other embodiments of the invention, an electric current is applied to the device to cause the clamp rings **210, 215** to wrap and clamp around the muscle. In those embodiments, forceps **550** may provide the conduit for conducting the necessary electrical current.

[00032] Referring to **FIG. 6**, the papillary muscle **560** is cut or severed at **570** between clamp rings **210, 215** (Block **860**). In one embodiment, the muscle is cut with a surgical blade. In another embodiment, the muscle is cut by an electrical current applied by the forceps. In another embodiment, the muscle is cut by any appropriate cutting tool, such as a laser.

[00033] Next, clamp ring **215** slides along the connecting rods **220** and away from clamp ring **210** (Block **870**). Tension applied by normal cardiac movement will slide rings **210, 215** apart and provide elongation of the papillary muscle. At this step, the device appears generally as illustrated in **FIG. 7**. Sliding clamp rings **210, 215** apart provides separation of the cut muscle sections to elongate the papillary muscle. Alternatively, the clamp rings may be slid along the connecting rods by forceps **550**.

[00034] Finally, the catheter and gripping device are retracted from the body, leaving the device surrounding the muscle in the clamping configuration (Block **880**). The elongated muscle tissue is allowed to form scar tissue around the device. Method **800** ends at Block **890**.

[00035] **FIG. 7** depicts the muscle elongation device deployed upon the posterior papillary muscle **560**. The illustration of treatment of the posterior papillary muscle in no way limits the invention, as the device may be employed on any papillary muscle, and indeed, the device may be used on any appropriate muscle tissue. As shown in **FIG. 7**, clamp rings **210, 215** wrap around the posterior papillary muscle and are connected by connecting rods **220**. In **FIG. 7**, two connecting rods are shown, although any number of connecting rods may be used to practice the invention.

[00036] It is important to note that **FIGS. 1-8** illustrate specific applications and embodiments of the present invention, and are not intended to limit the scope of the present disclosure or claims to that which is presented therein. For example, the muscle elongation system of the present invention can be used for other heart valves, such as a tricuspid valve, in addition to the mitral valve. The muscle elongation system of the present invention may also be used on muscles other than a papillary muscle. Different arterial and venous approaches can also be used. Upon reading the specification and reviewing the drawings hereof, it will become obvious to those skilled in the art that myriad other embodiments of the present invention are possible, and that such embodiments are contemplated and fall within the scope of the presently claimed invention.

[00037] While the embodiments of the invention disclosed herein are presently considered to be preferred, various changes and modifications can be made without departing from the spirit and scope of the invention. The scope of the invention is indicated in the appended claims, and all changes that come within the meaning and range of equivalents are intended to be embraced therein.

CLAIMS

1. A system for treating a dilated heart valve comprising:

a delivery device 100 comprising a delivery catheter 110 and a holding catheter 130;

a muscle elongation device 200 coupled to the holding catheter 130 and received in the delivery catheter 110, the muscle elongation device 200 including at least one clamping device 215 and disposed adjacent a distal end 116 of the holding catheter 110, the at least one clamping device 215 slidably disposed on an at least one connecting rod 220, wherein when the system is delivered to a muscle region associated with the dilated heart valve, the muscle elongation device 200 is released from the delivery catheter 110 and the at least one clamping device 215 wraps around the muscle region.

2. The system of claim 1 wherein the muscle elongation device 200 includes a first clamping device 210 fixedly attached to the at least one connecting rod 220 and a second clamping device 215 slidably disposed on the at least one connecting rod 220.

3. The system of claim 1 wherein the delivery catheter further comprises a side delivery port 114 located adjacent the distal end 116 of the delivery catheter 110.

4. The system of claim 3 wherein the side delivery port 114 further comprises two restraining members 340.

5. The system of claim 1 further comprising a locating device.

6. The system of claim 5 wherein the locating device comprises a balloon.

7. The system of claim 5 wherein the locating device comprises a guide wire.

8. The system of claim 1 wherein the holding catheter comprises biopsy forceps 550.

9. The system of claim 1 wherein the at least one clamping device 210, 215 comprise a shape-memory material.

10. The system of claim 9 wherein the shape-memory material is an elastic shape-memory material.

11. The system of claim 9 wherein the shape-memory material is a thermal shape-memory material.

12. The system of claim 9 wherein the shape-memory material is a material chosen from a group consisting of stainless steel, nitinol, tantalum, cobalt nickel alloy, platinum, titanium, a thermoplastic or thermoset polymer, or a combination thereof.

13. The system of claim 1 wherein the connecting rod 220 comprises an at least one stop 230 disposed at a proximal end of the connecting rod.

14. The system of claim 13 wherein the connecting rod 220 comprises a second stop 235 disposed at a distal end of the connecting rod.

15. A muscle elongation device 200 for treatment of a dilated heart valve, comprising:

at least one connecting rod 220;

a first clamping device 210 fixed to the at least one connecting rod; and

a second clamping device 215 slidably disposed along the connecting rod,

wherein the first clamping device 210 and the second clamping device 215 have a first diameter in a delivery configuration and a second diameter in a clamping configuration, the second diameter less than the first diameter.

16. The muscle elongation device of claim 15 further comprising:

at least one stop 230 disposed on the at least one connecting rod 220.

17. The muscle elongation device of claim 15 wherein the muscle elongation device 200 is composed of a shape memory material.

18. The muscle elongation device of claim 17 wherein the shape memory material is an elastic shape memory material.

19. The muscle elongation device of claim 17 wherein the shape memory material is a thermal shape memory material.

20. The muscle elongation device of claim 17 wherein the shape-memory material is a material chosen from a group consisting of stainless steel, nitinol, tantalum, cobalt nickel alloy, platinum, titanium, a thermoplastic or thermoset polymer, or a combination thereof.

21. A method for treating a dilated heart valve, the method comprising:

delivering a muscle elongation device 200 in a lumen of a delivery catheter 110 proximate a dilated heart valve;

positioning at least two clamping devices 210, 215 disposed along at least one connecting rod 220 of the muscle elongation device 200 on a muscle region 560 proximate the dilated heart valve;

releasing the muscle elongation device 200 from the delivery catheter 110;

wrapping the clamping devices 210, 215 about the muscle region 560;

cutting the muscle between the clamping devices 210, 215 ; and

sliding the clamping devices 210, 215 away from each other along the connecting rod.

22. The method of claim 21 further comprising locating the cardiac muscle with a location device.

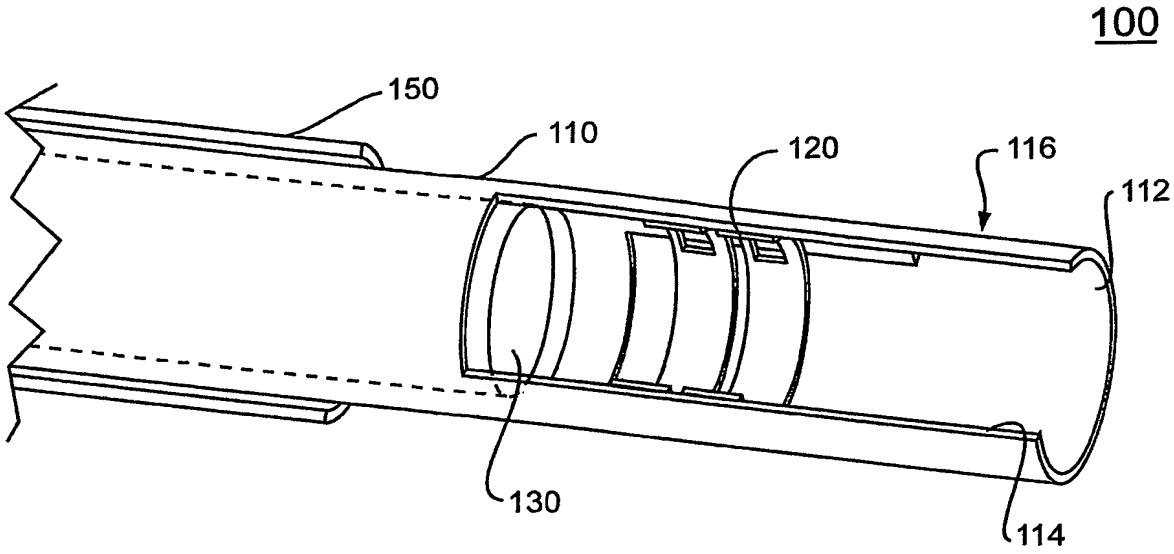


FIG. 1

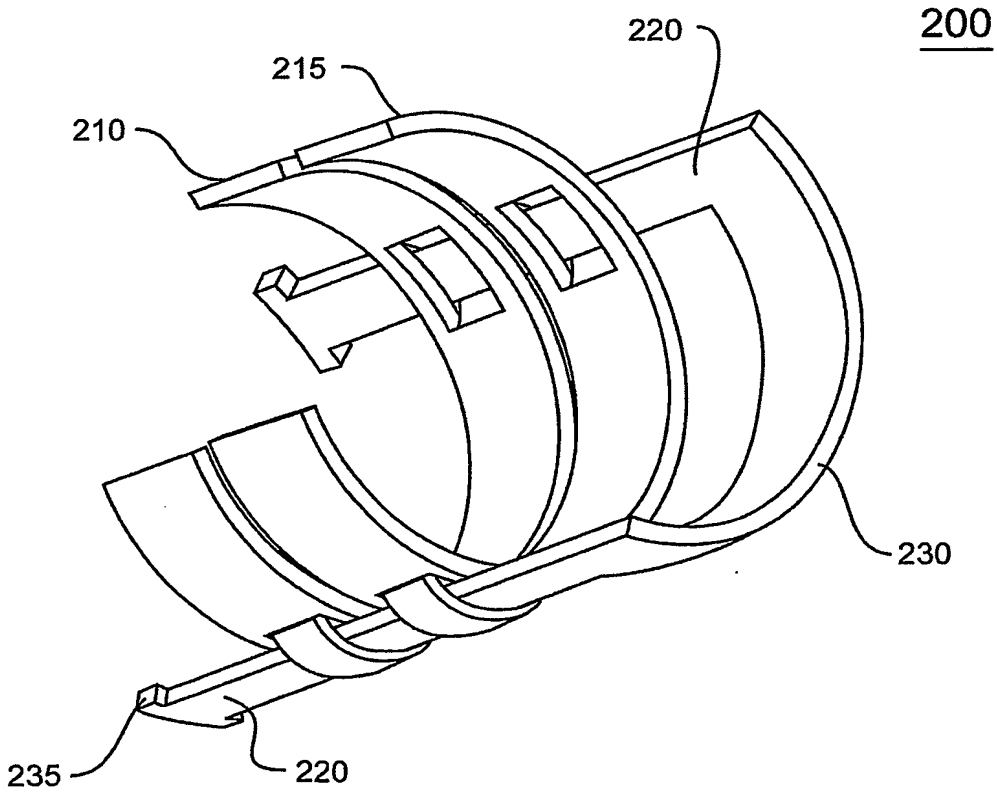


FIG. 2

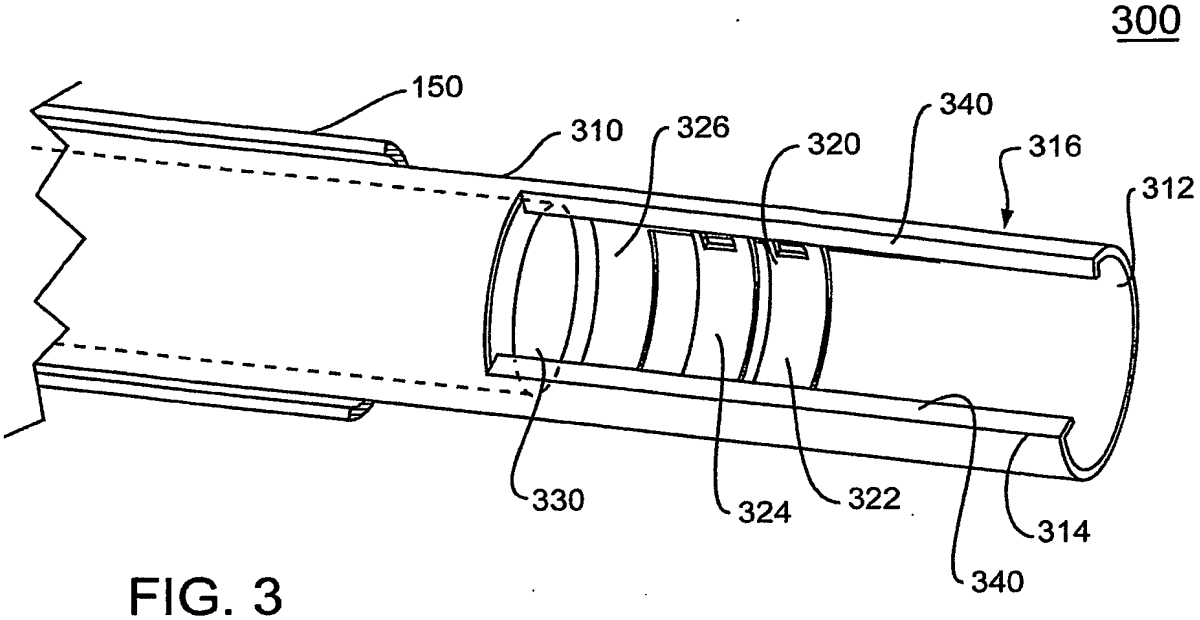

300
150
310
326
320
340
316
312
330
324
322
314
340

FIG. 3

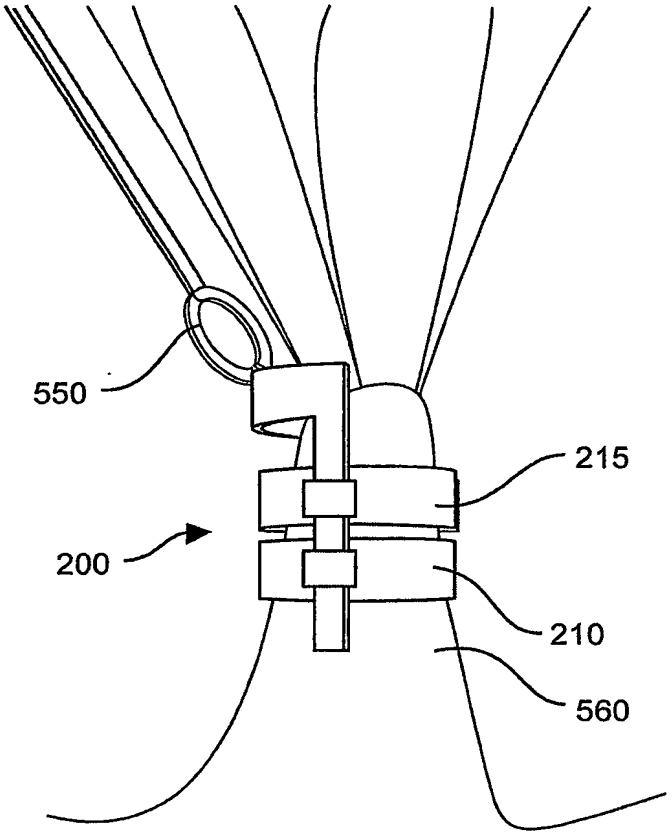

550
215
200
210
560

FIG. 5

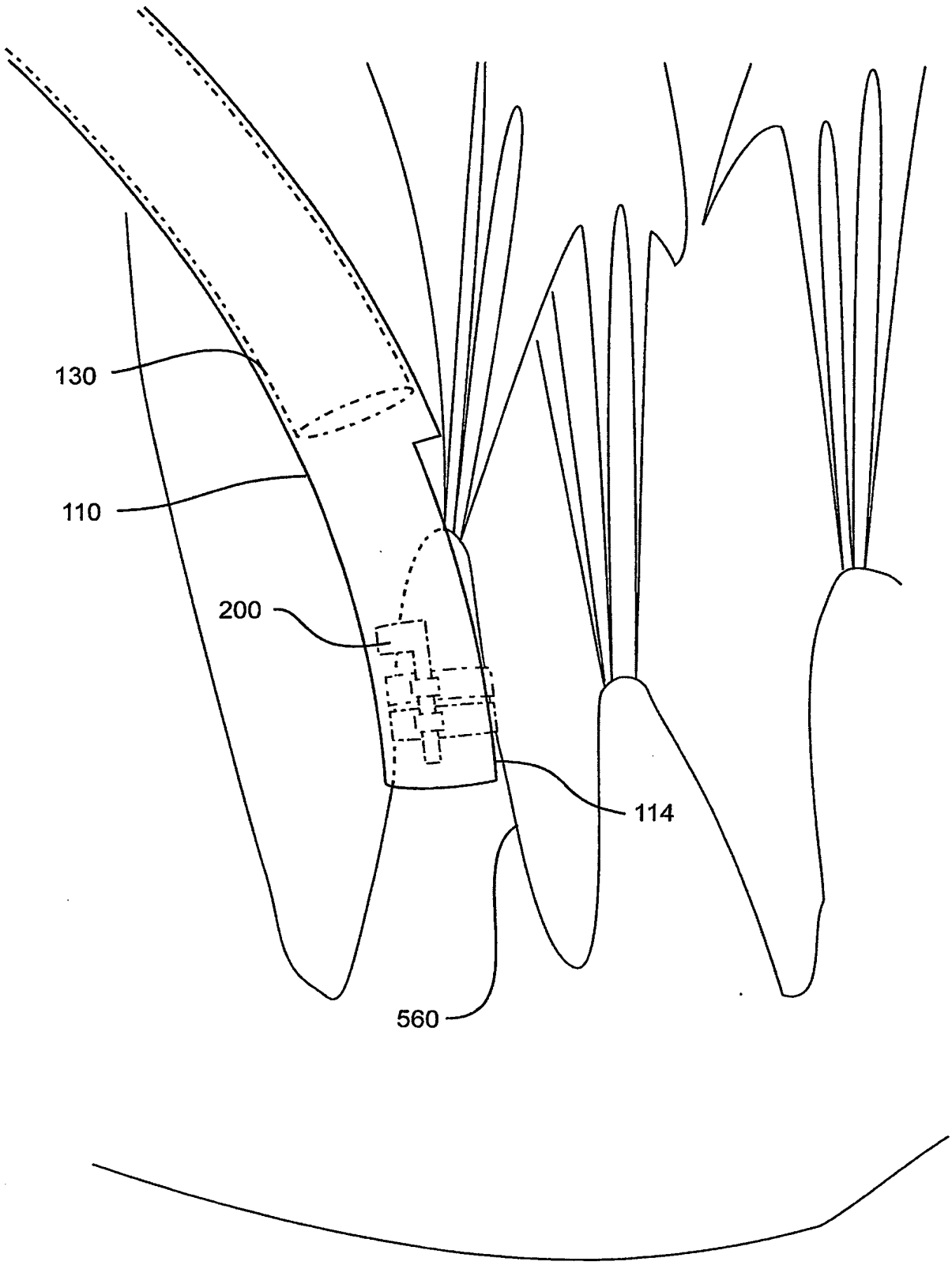
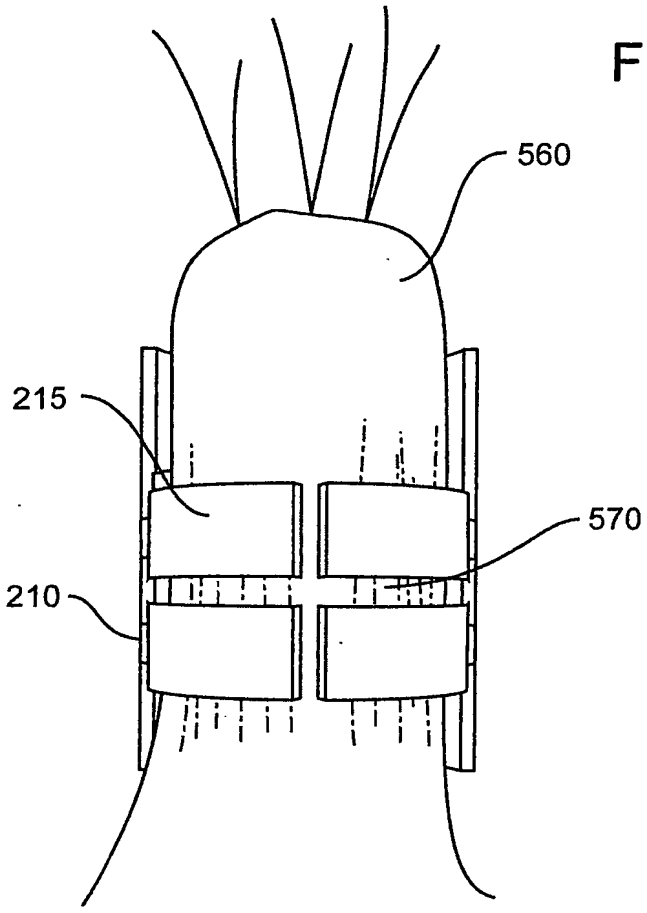


FIG. 4

FIG. 6



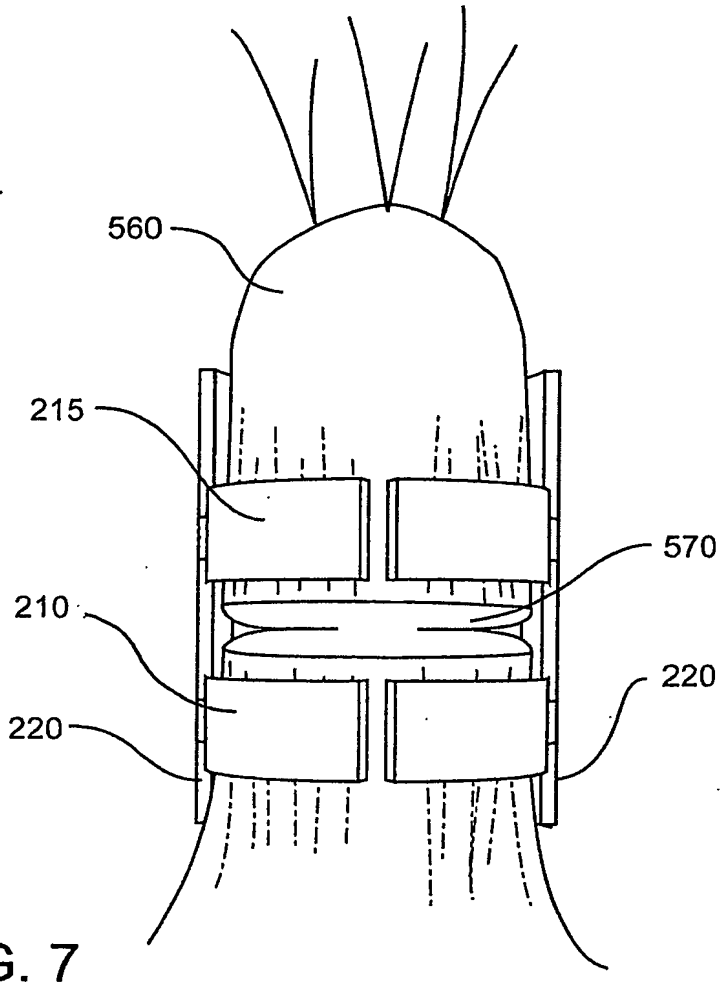
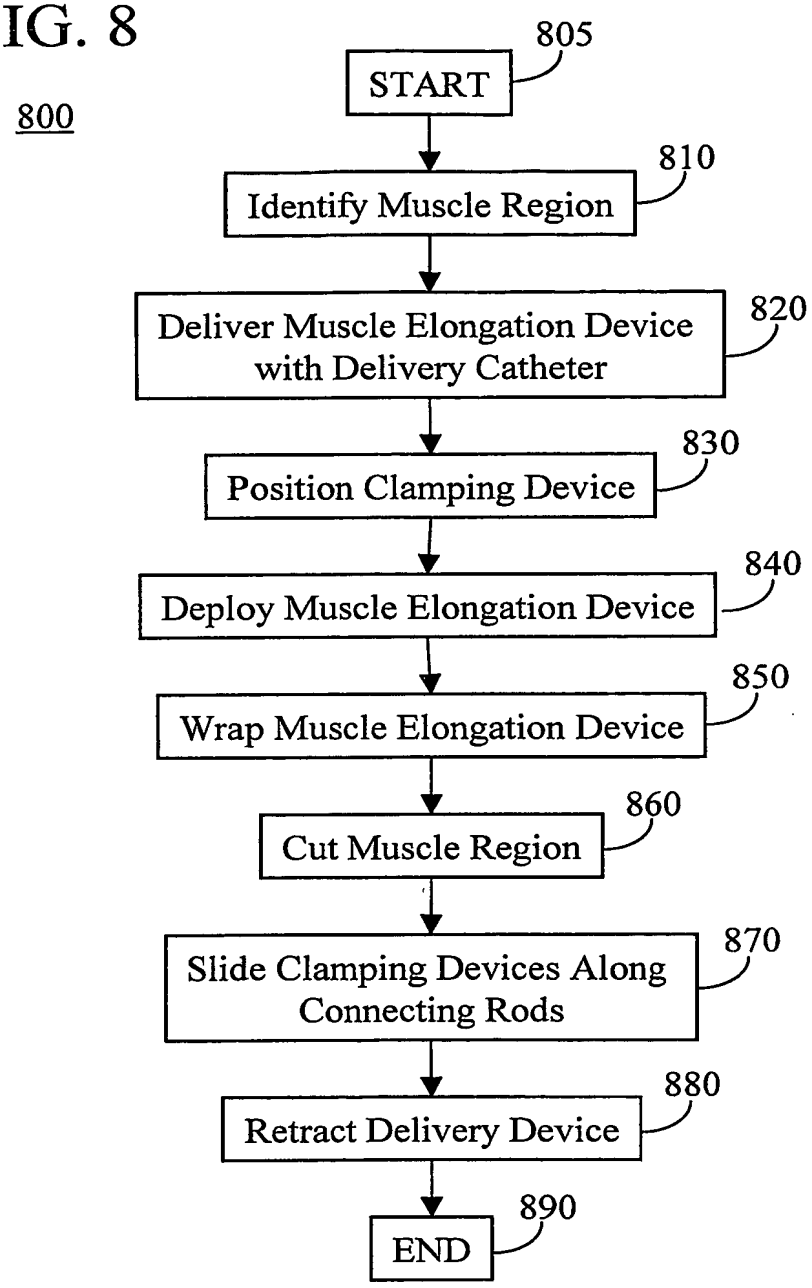


FIG. 7

FIG. 8


800
805
START
810
Identify Muscle Region
820
Deliver Muscle Elongation Device with Delivery Catheter
830
Position Clamping Device
840
Deploy Muscle Elongation Device
850
Wrap Muscle Elongation Device
860
Cut Muscle Region
870
Slide Clamping Devices Along Connecting Rods
880
Retract Delivery Device
890
END

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US2004/030083

Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 21, 22
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/030083

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2003083742 A1	01-05-2003	US 2004088047 A1	06-05-2004
		US 2005070999 A1	31-03-2005

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2004/030083

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61F2/24

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61F A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2003/083742 A1 (SPENCE PAUL A ET AL) 1 May 2003 (2003-05-01) paragraph '0029! paragraph '0069! - paragraph '0070! figures 19,20	1

☐ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"A" document defining the general state of the art which is not considered to be of particular relevance

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Date of the actual completion of the international search	Date of mailing of the international search report
30 May 2005	08/06/2005

Name and mailing address of the ISA	Authorized officer
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